Exhibit 1

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCIATION *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*,

Defendants.

Case No. 1:23-cv-00707

EXPERT DECLARATION OF
PROFESSOR THOMAS C. BUCHMUELLER, PH.D.

I. INTRODUCTION

A. Qualifications

1. I am the Waldo O. Hildebrand Professor of Risk Management and Insurance and Professor of Business Economics and Public Policy at the University of Michigan's Stephen M. Ross School of Business. From 2012 to 2019, I was Chair of the Ross School's Business Economics and Public Policy Area, and from 2020 to 2023, I was the school's Senior Associate Dean for Faculty and Research. I also hold an appointment in the Department of Health Management and Policy in the University of Michigan's School of Public Health. From 2012 to 2018, I was a member of the Institutional Leadership Team of the University's Institute for Health Policy and Innovation.
2. I received my Ph.D. in Economics from the University of Wisconsin-Madison in 1992 and my B.A. in Economics from Carleton College in 1985. Prior to joining the University of Michigan faculty in 2006, I was a tenured full professor at the University of California, Irvine's Paul Merage School of Business.
3. I am a Research Associate of the National Bureau of Economic Research. In 2014, I was elected as a member of the Board of Directors of the American Society of Health Economists (ASHEcon). From 2018 to 2023, I was Editor-in-Chief of the *American Journal of Health Economics*, the official journal of ASHEcon. Previously, I was a co-editor of *BE Journal of Economic Analysis and Policy*, the *Journal of Economics and Management Strategy* and *Medical Care*.
4. I have done two stints of Federal government service. From 2011 to 2012, I was the Senior Health Economist at the White House Council of Economic Advisers. From 2023 to 2025, I was Deputy Assistant Secretary for Planning and Evaluation (ASPE) in the

Department of Health and Human Services. At ASPE, I directed the Office of Health Policy. In addition, in 2023 I was named to the National Advisory Council of the Agency for Health Care Research and Quality. When I took the position at ASPE, I became an ex officio member of this committee.

5. I am a health economist whose research focuses mainly on public policy issues related to health insurance. I have published my research in top journals in economics, health services research and health policy. While at ASPE, I oversaw several research projects on the prescription drug provisions of the Inflation Reduction Act (IRA) as well as other studies on Medicare and prescription drugs. A copy of my curriculum vitae is attached to this report (Appendix A).

B. Assignment

6. I have been asked to evaluate the declaration of the plaintiff's expert, Professor Craig Garthwaite. Specifically, I have been asked to respond to the argument that the Medicare Drug Price Negotiation Program is not a true negotiation, but rather a coercive price-setting scheme in which manufacturers have zero leverage, and the Centers for Medicare & Medicaid Services (CMS) has infinite leverage.

7. My analysis is based on my training as an economist, over 30 years of experience as an academic health policy researcher, and a review of academic research and other publicly available materials about the IRA and drug price negotiations. Appendix B lists the references I have used in preparing this report. My hourly rate of compensation is $700.

C. Analysis

Professor Garthwaite Presents a Distorted and Misleading Representation of Medicare Drug Price Negotiations

8. In Section IV.C. of his declaration, Professor Garthwaite argues that the Medicare Drug Price Negotiation Program does not represent a true negotiation but rather is a price-setting program. This characterization is inaccurate, as it ignores key elements of negotiations in general and key features of the Medicare Drug Price Negotiation Program in particular. Despite his credentials as an academic economist, Garthwaite's assessment of the Medicare Drug Price Negotiation Program is curiously devoid of economic logic.

9. The standard economic approach used to analyze bilateral negotiations is a Nash Bargaining Framework. In this framework, the outcome depends importantly on the difference between the payoff each party receives if the negotiation is successful and their payoff if they walk away from the negotiation or if the negotiation fails. The latter outcome is what Garthwaite refers to as the best alternative to a negotiated agreement (BATNA).

10. Professor Garthwaite promises in his declaration to "examine what the BATNAs look like for manufacturers and CMS,"[1] though in fact he considers only the situation of the manufacturers. Although he discusses the incentives facing manufacturers at some length,[2] tellingly, he never offers any remotely comparable analysis of the incentives facing CMS. By ignoring CMS' perspective and the consequences to CMS of a failed negotiation, he presents a highly distorted picture of the program. And while he at least purports to address manufacturer incentives, Garthwaite offers limited insights about

[1] Garthwaite Declaration ¶ 84.
[2] Garthwaite Declaration ¶¶ 86-91.

manufacturers' BATNA. Rather, he merely complains the penalties for not participating in the negotiation process are excessively harsh. His complaint ignores a fundamental aspect of negotiations, which is that negotiations can succeed only if the cost of not participating is high for both parties. As noted by leading health economists[3] and the Congressional Budget Office (CBO),[4] without such costs, the parties would not be sufficiently motivated to come to an agreement.

11. Garthwaite barely acknowledges CMS' objectives and constraints, and when he does his statements are incomplete and highly misleading. He writes

> Because of the broad latitude the IRA grants CMS alongside the extreme penalties it imposes on manufacturers who reject the [maximum fair price (MFP)] set by CMS, Congress has effectively given CMS the unfettered power to set prices for eligible drugs. Indeed, so unconstrained are these prices that CMS could conceivably set a $0 MFP. From an economic perspective, manufacturers (particularly those that sell multiple products), would be better off accepting an offer close to a zero price (or even a negative price, i.e., pay CMS for the right to provide the drug to Medicare participants) than face either of the onerous and financially unsustainable alternatives. Even if such absurd prices were not set by CMS, manufacturers would constantly face the threat that they could be, creating substantial economic uncertainty.[5]

Preliminarily, Garthwaite is incorrect that the MFP is "set by CMS."[6] By statutory definition, the "maximum fair price" is the price "negotiated" pursuant to Section 1194 of the Social Security Act.[7] More to the point, the idea that CMS would seek to negotiate for prices near zero is indeed absurd. A much more reasonable characterization of CMS' objective, consistent with basic economic principles, is that CMS is concerned with both

[3] Frank, Richard G., and Len M. Nichols. "Medicare drug-price negotiation—why now... and how." *New England Journal of Medicine* 381, no. 15 (2019): 1404-1406.
[4] Congressional Budget Office, letter to the Honorable Ron Wyden (April 10, 2007), www.cbo.gov/publication/18550; and Congressional Budget Office, letter to the Honorable Chuck Grassley (May 17, 2019), www.cbo.gov/publication/55270.
[5] Garthwaite Declaration ¶ 78.b.
[6] *Id.*
[7] 42 U.S.C. § 1320f(c)(3).

the clinical benefits of each negotiated drug (relative to therapeutic alternatives) and the cost of the negotiated drugs to taxpayers. A failed negotiation would deny those clinical benefits to Medicare beneficiaries, which is an outcome that CMS has strong policy and political incentives to avoid. The drugs selected for the first round of negotiations treat serious health conditions, including blood clots, diabetes, heart disease, arthritis and cancer, that are highly prevalent among the Medicare population. According to a report by ASPE, in 2022 roughly 3.5 million Medicare enrollees took Eliquis and over 1 million took Jardiance and Xarelto.[8] In total, roughly 7.7 million took one or more of the selected drugs. Although there are alternative treatments in many cases, there could be serious health and financial consequences if patients lost access to one or more of the selected drugs. Indeed, costs of a failed negotiation could include higher Medicare and Medicaid spending if the lack of access to drugs that have been withdrawn leads to greater use of other types of care (*e.g.*, emergency department visits and hospitalization).[9] Depending on the availability of therapeutic alternatives, a failed negotiation could result in increased out-of-pocket expense for Medicare beneficiaries.

[8] ASPE, Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs, Inflation Reduction Act Research Series, December 14, 2023.

[9] Studies using a variety of research designs and data sources find that improved coverage of prescription drugs leads to reductions in spending on other types of medical care. These studies include analyses using cross-sectional data comparing Medicare beneficiaries with different degrees of drug coverage (*see, e.g.*, Hsu, J., Price, M., Huang, J., Brand, R., Fung, V., Hui, R., Fireman, B., Newhouse, J.P. and Selby, J.V., 2006. Unintended consequences of caps on Medicare drug benefits. *New England Journal of Medicine*, *354*(22), pp.2349-2359), studies exploiting changes in coverage caused by the establishment of Medicare Part D (*see, e.g.*, Zhang, Y., Donohue, J.M., Lave, J.R., O'Donnell, G. and Newhouse, J.P., 2009. The effect of Medicare Part D on drug and medical spending. *New England Journal of Medicine*, *361*(1), pp.52-61), and research analyzing the effect of increased cost-sharing for prescription drugs (Chandra, A., Gruber, J. and McKnight, R., 2010. Patient cost-sharing and hospitalization offsets in the elderly. *American Economic Review*, *100*(1), pp.193-213).

12. In addition to the direct impact on beneficiaries, there would be a substantial political cost associated with a failed negotiation. Chen et al. make this point in a recent article in *Health Affairs Forefront*:

> In fact, CMS is likely just as motivated as manufacturers to avoid a failed negotiation or their departure from the program. After all, even proposing to limit beneficiaries' access to certain medications can have swift political consequences.[10]

Similarly, Rodwin and Lantos note:

> The manufacturer could withdraw from Medicare and Medicaid if selling at that price would not be profitable. This would create a political backlash, particularly if there is a need for a particular drug when there are no suitable alternatives. … CMS may therefore accept a price higher than it believes is most fair to secure a contract and preclude the possibility of market exit and political backlash.[11]

13. Indeed, CMS has previously constrained its decision-making based in part on political considerations. The case of Medicare Part D coverage of "protected class" drugs provides a good example. Since the Part D program was established, Medicare prescription drug plans have been required to cover nearly all drugs in six protected classes: antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics. This requirement reduces the bargaining power of private Part D plans, leading to rebates that are significantly lower for protected class drugs than for drugs that plans can exclude from their formularies.[12] In a proposed rule announced in November 2018, CMS considered allowing Part D plans to

[10] Chen, Jennifer C., Nancy Le, Steve Jang and Anna Koeltenboeck, "What Medicare Negotiation Tells Us About Drug Pricing in the U.S.," *Health Affairs Forefront*, (2024), available at https://www.healthaffairs.org/content/forefront/medicare-negotiation-tells-us-drug-pricing-u-s.
[11] Rodwin, Marc A. and John D. Lantos, "How Will Medicare Negotiate Drug Prices, And What Impact Will It Have?" *Health Affairs Forefront*, (2024), available at https://www.healthaffairs.org/content/forefront/medicare-negotiate-drug-prices-and-impact-have.
[12] Kakani, Pragya, Michael Anne Kyle, Amitabh Chandra, and Luca Maini, "Medicare Part D Protected-Class Policy is Associated with Lower Drug Rebates, *Health Affairs*, 43 no. 10 (2024): 1420-1427.

exclude protected class drugs from their formularies under certain circumstances.[13] CMS estimated that this would save the program $1.85 billion over ten years.[14] However, in response to concerns expressed by commenters, including from the pharmaceutical industry and patient groups,[15] CMS ultimately backed off from adopting these changes.[16] This example highlights the political sensitivities related to Part D drug coverage and enrollees' access to prescription drugs.[17]

14. Professor Garthwaite argues that it is possible that the decision of a manufacturer to not participate in the negotiation might actually lead to an increase in Medicare spending if that decision required the firm to withdraw other, lower cost drugs from Medicare.[18] This hypothetical ignores the possibility that a firm that rejected negotiation could transfer ownership of the selected drug to another entity while continuing to participate in Medicare and Medicaid.[19] But if such a spillover effect were possible, it would only increase the cost to CMS of a failed negotiation—not just for Medicare, but also for Medicaid—which would increase the manufacturer's leverage and temper CMS' efforts to push for lower prices. Thus, assuming rational behavior on the part of CMS, the type

[13] Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152, 63152 (2018) (proposed rule).
[14] *See id.* at 63153.
[15] Sarah Owermohle and Sarah Karlin-Smith, "Patient groups, pharma cheer CMS retreat on protected class change," *Politico* (May 17, 2019).
[16] *See* Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 84 Fed. Reg. 23832, 23832 (2019) (final rule).
[17] As this example illustrates, it can often be difficult to distinguish between factors that influence policymakers' decisions through an effect on beneficiaries and political constraints. Here, as in many situations, CMS faced a tradeoff between ensuring broad access to important medications and controlling health care spending. Pharmaceutical manufacturers and patient advocates objecting to the proposed rule emphasized the importance of access. It is not possible, nor is it empirically meaningful, to say whether CMS was convinced by the strength of the arguments made in the comment and review process or simply calculated that the benefit of allowing Part D plans to exclude certain protected class drugs was not worth the political cost.
[18] Garthwaite Declaration ¶ 85 fn. 190.
[19] *See* Final Guidance 40.7 (detailing steps a manufacturer could take to transfer ownership of selected drug to another entity while continuing to participate in Medicare and Medicaid).

of spillovers that Garthwaite imagines would lead to *higher* negotiated prices, which would benefit manufacturers.[20]

An Accurate Representation of the Medicare Drug Price Negotiations Should be Based on a Standard Economic Approach for Analyzing Bilateral Negotiations

15. Beyond mentioning the concept of BATNA, Garthwaite does not use economic concepts to analyze the Drug Price Negotiation Program. As noted, a standard economic approach used to analyze bilateral negotiations is the Nash Bargaining Framework. In a 2021 white paper,[21] Adams and Herrnstadt describe how CBO used this framework to model the impact of Medicare drug price negotiations.[22] The paper models an earlier legislative proposal, the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3),[23] which resembles the IRA in some important ways.

16. In the CBO model, the benefit that CMS receives from a successful negotiation is the incremental health benefit the drug provides to Medicare beneficiaries (relative to the next-best therapeutic alternative) minus the cost of the drug. The CBO model incorporates the reality that a failed negotiation is costly to both manufacturers and CMS. Importantly, the relative leverage held by CMS and manufacturers varies across drugs depending on the extent to which there are good therapeutic alternatives and the cost of

[20] In fact, one could argue that requiring manufacturers that reject negotiations to withdraw all of their products from Medicare and Medicaid allows those firms to tie their different products in a manner that would otherwise create an antitrust enforcement risk.
[21] Adams, Christopher and Evan Herrnstadt, "CBO's Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act," Congressional Budget Office Working Paper 2021-01, available at https://www.cbo.gov/publication/56905.
[22] The Nash Bargaining Framework has been used to model negotiations between private insurers and drug manufacturers. See Lakdawalla, Darius, "Economics of the Pharmaceutical Industry," *Journal of Economic Literature*, 56 no. 2 (2018): 397-449.
[23] https://www.congress.gov/bill/116th-congress/house-bill/3.

those alternatives. When a drug provides substantial clinical benefits relative to the next best alternative, the cost of a failed negotiation, measured in terms of the forgone benefits to patients, will be high. In contrast, in cases where there are reasonable substitutes for a selected drug, the cost of failure will be much lower.[24] Accordingly, the model predicts that the discounts that CMS will be able to achieve through negotiation will be different for different drugs.

17. CBO's model includes bargaining weights, which determines how the surplus from a successful negotiation would be divided. These weights, which are defined to sum to one, can be seen as representing each side's bargaining power. As such, they incorporate factors like each side's willingness to hold out for a more favorable result, their negotiating skills, and the political and public relations costs associated with a failed negotiation. The assumption that CMS held all the power to determine the negotiated price and manufacturers held no power would translate to a bargaining weight of one for CMS and a weight of zero for the manufacturer. In their preferred specification, CBO assumes that the bargaining weight for each side is 0.5. In other words, they assume that CMS and manufacturers have equal bargaining power.

18. A key input to the model is the prices of the selected drugs in the absence of the negotiation program. The relevant prices are net prices after discounts and rebates arising

[24] Notably, Congress designed the Drug Price Negotiation Program such that CMS selects and negotiates drugs for which there is unlikely to be a close substitute and there is therefore likely to be a higher cost of failure. First, drugs eligible for selection must have been marketed for seven years without a generic (or eleven years without a biosimilar for biological products). *See* 42 U.S.C. § 1320f-1(e)(1); Final Guidance § 30.1. Second, selection and negotiation is delayed when the Secretary determines there is a high likelihood of (or significant progress toward) biosimilar market entry. *See* 42 U.S.C. § 1320f-1(f); Final Guidance § 30.3.1. Third, a drug will be deselected if the Secretary determines a generic or biosimilar is available and marketed; and the MFP, if already negotiated, will be lifted. *See* 42 U.S.C. § 1320f-1(e); Final Guidance § 70. Finally, once a drug is subject to negotiation (or renegotiation), CMS must consider information about therapeutic alternatives when negotiating the MFP. *See* 42 U.S.C. § 1320f-3(e)(2); Final Guidance § 50.2.

from negotiations with private Medicare Part D plans. Consistent with the Nash Bargaining Framework applied to those negotiations, negotiated prices will tend to be lower when the therapeutic class for a drug includes multiple competitors offering comparable health benefits. To the extent that private plans have been able to negotiate large discounts in such cases, the prices that CMS is able to negotiate may be significantly below list prices, but not that much lower than the net prices that Part D plans were already paying. The requirement to cover all drugs in the six protected classes greatly limits the leverage that Part D plans hold in their negotiations with drug manufacturers, leading to smaller insurer-negotiated discounts compared to those for drugs that can be excluded from a plan's formulary. Thus, for protected class drugs there is greater potential for CMS to negotiate meaningful discounts not only relative to list prices but also compared to net prices negotiated by Part D plans.

19. Like the IRA, H.R. 3 would have constrained the MFP to be at or below a ceiling. In the IRA, the ceiling is determined by the lesser of the net Medicare price of the drug or a required discount off of the drug's non-federal average manufacturer price, which is the average wholesale price paid by non-federal purchasers. In H.R. 3, the ceiling equaled 120 percent of the average market price in six other countries (Australia, Canada, France, Germany, Japan, and the United Kingdom). H.R. 3 also included a lower bound for the MFP, equal to the lowest price in these six countries. If, as Garthwaite asserts, CMS has unchecked power to demand low prices and would choose to use that power, the outcome of the model would be a price near the lower bound. But this is not what the CBO model predicts. Rather, the model predicts that for most drugs the negotiated prices will be close to the upper bound. The explanation for this result goes back to the significant cost that

CMS would bear in the event that negotiations failed. The cost of a failed negotiation is especially high for drugs where the clinical benefits relative to the next best therapeutic alternative are large, giving manufacturers greater leverage.

The Results of the First Round of Negotiations are Consistent with a True Negotiation Process and Inconsistent with Professor Garthwaite's Analysis

20. Professor Garthwaite's original declaration was written before the MFPs for initial price applicability year (IPAY) 2026 were announced.[25] After those prices were announced, he updated his declaration slightly to acknowledge those results.[26] However, his discussion of the actual results is brief, selective, and uninformative. A fair assessment of the actual negotiation process and the resulting MFPs indicates a set of ten negotiations in which each party bargained in good faith and the results reflected the specific clinical and market context for each selected drug.

21. The statute requires CMS to publish explanations for how the MFP for each of the 10 drugs was determined.[27] In addition to providing information specific to each drug, these explanations provide an overall description of how the negotiations played out. For each drug, CMS and the manufacturers met three times. The meetings permitted face-to-face interaction between the parties (either in person or virtually). Indeed, the large majority

[25] ECF No. 35-1.
[26] Garthwaite Declaration ¶¶ 92-95.
[27] The explanations are available at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

of these meetings were in person,[28] consistent with best practices for complex negotiations of this sort.[29]

22. During the meetings, CMS revised its initial offer at least once for each manufacturer. Across the first cycle of negotiations for all ten selected drugs, more than 50 revised offers or counteroffers were proposed by CMS or a Primary Manufacturer—not including the ten initial offers CMS made and the ten written counteroffers provided by Primary Manufacturers. For five of the ten drugs, the two parties agreed to a price in association with a negotiation meeting. In four of these five cases, CMS accepted a revised counteroffer from the manufacturer. In the other five cases, the manufacturer accepted CMS' final offer. The negotiated price was closer to CMS' initial offer in four of the ten cases and closer to the manufacturer's first counteroffer in six of the ten cases. This back-and-forth along with the variation in how the MFPs compared to the initial offers and counteroffers is reflective of a true negotiation process in which the outcomes were determined by factors specific to each drug and the information presented by both sides. Different researchers have evaluated the MFPs, comparing them to ceilings established by the statute and estimates of each drug's net Medicare Part D price before negotiations.[30] In his declaration, Garthwaite reproduces a table from one of those

[28] The MFP explanations posted on the CMS website include summaries of each meeting. For 21 of the meetings, the full participant list is provided; for the other 9, the list of manufacturer participants is redacted. Among the 21 non-redacted meetings, 20 were conducted in-person (occasionally with one person attending remotely).
[29] Frank, Richard G. and Gerald F. Anderson, letter to Meena Seshamani commenting on Medicare Drug Price Negotiation Program Draft Guidance (July 1, 2024). https://www.brookings.edu/articles/comments-on-the-medicare-drug-price-negotiation-program/.
[30] Because actual net prices are confidential, researchers must estimate net prices using several different data sources. For example, see Hernandez, Inmaculada, Emma M. Cousin Olivier J. Wouters, Nico Gabriel, Teresa Cameron and Sean D. Sullivan, "Price Benchmarks of Drugs Selected for Medicare Price Negotiations and their Therapeutic Alternatives," *Journal of Managed Care Specialty Pharmacy*, 30 no. 8 (2024): 762-772.

studies.[31] The data indicate heterogeneity in the difference between the IPAY 2026 MFP for a selected drug and its estimated net price prior to negotiation of the MFP. Garthwaite says that the "variation in discounts across the ten drugs reflects part of the uncertainty that drug manufacturers face."[32] The authors of the article he cites interpret the results much differently, saying that the observed variation can be explained by economic factors, such as the degree of competition that different drugs face. For example, they note that negotiations produced very similar discounts for Eliquis and Xarelto, two drugs that are therapeutic alternatives to each other, and therefore face similar market conditions. Similarly, another study assessing the MFPs produced by the first year of negotiations concludes that the extent to which there are close therapeutic substitutes for a selected drug is a key factor explaining the variation in negotiated prices.[33] The fact that basic economic factors can rationalize the variation in MFPs resulting from negotiation undermines Garthwaite's argument regarding the uncertainty that manufacturers face.

23. Another key finding from these studies is that for some of the selected drugs, the MFPs are only slightly lower than the estimated net prices that Part D plans were already paying.[34] This result goes against Garthwaite's assertion that the negotiation program gives CMS unchecked power to demand extremely low prices. Professor Garthwaite effectively acknowledges that the results of the first round of negotiations contradict his

[31] Hernandez, Inmaculada, Olivier J. Wouters, Emma M. Cousin, Ayuri S. Kirihennedige and Sean D. Sullivan, "Interpreting The First Round of Maximum Fair Prices Negotiated By Medicare For Drugs," *Health Affairs Forefront*, (2024), available at https://www.healthaffairs.org/content/forefront/interpreting-first-round-maximum-fair-prices-negotiated-medicare-drugs.
[32] Garthwaite Declaration ¶ 93.
[33] Chen, Jennifer C., Nancy Le, Steve Jang and Anna Koeltenboeck, "What Medicare Negotiation Tells Us About Drug Pricing in the U.S.," *Health Affairs Forefront*, (2024), available at https://www.healthaffairs.org/content/forefront/medicare-negotiation-tells-us-drug-pricing-u-s.
[34] *See also* Anderson-Cook, Anna and Richard G. Frank, "Impact of Federal Negotiation of Prescription Drug Prices," The Brookings Institution (August 19, 2024), available at https://www.brookings.edu/articles/impact-of-federal-negotiation-of-prescription-drug-prices/.

dire predictions by asserting without explanation that "the outcomes of this first round of price setting are not necessarily reflective or predictive of future outcomes."[35]

24. Other analyses compare the MFPs produced by the first round of negotiations to international prices for the same drugs. Table 1, which reproduces results from one such study[36] compares the IPAY 2026 MFPs to average 2024 prices in 11 other high-income countries within the Organisation for Economic Co-operation and Development (OECD).[37] In contrast to the small difference between the MFPs and the estimated net prices that Part D plans were already paying, the international comparison indicates that even after negotiation, prices are dramatically higher in the U.S. than in peer countries. For example, consider the case of Eliquis, which in 2022 had the highest gross Medicare spending of the 10 selected drugs. According to the estimates presented in the study that Garthwaite cites, the MFP for Eliquis is just 9 percent lower than the estimated net price that Part D plans paid in 2023. In contrast, the MFP for Eliquis is 228 percent higher than the average price in the 11 peer countries. Eliquis is not an outlier in this respect. For 8 of the 10 drugs, the 2026 MFP is more than twice the average 2024 price for the comparison countries and for 5 of the drugs, the MFP is more than 3 times the average. For all but one drug, the MFP is higher than the highest price in any other country. For that one exception (Stelara) the MFP is still 60 percent higher than the 11-country average.[38]

[35] Garthwaite Declaration ¶ 95.
[36] Tevis, Delaney, Matthew McGough, Juliette Cubanski and Cynthia Cox, How Medicare Negotiated Drug Prices Compare to Other Countries, Peterson-KFF Health System Tracker, December 19, 2024, available at: https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/
[37] The 11 countries are: Australia, Austria, Belgium, Canada, France, Germany, Japan, Netherlands, Sweden, Switzerland and the United Kingdom. The results are essentially the same if the comparison group is limited to the six countries that would have served as the reference in H.R. 3.
[38] In the data reported by Tevis et al, the price of Stelara is highest in Germany. Another study using different data finds that the MFP for Stelara is lower than the list price in Germany. See Wouters, Olivier J., Sean D. Sullivan, Emma M. Cousin, Nico Gabriel, Irene Papanicolas, and Inmaculada Hernandez. "Drug Prices Negotiated by Medicare vs US Net Prices and Prices in Other Countries." *JAMA* 333, no. 1 (2025): 85-87.

Table 1. Comparing Maximum Fair Prices to Average Prices in 11 OECD Countries

		11 Comparison Countries, 2024		
	MFP, 2026	**Average**	**min**	**max**
Eliquis	$248.70	$75.86	$45.01	$104.34
Jardiance	$203.82	$52.45	$35.28	$86.88
Xarelto	$206.43	$81.64	$42.69	$137.65
Farxiga	$181.59	$54.11	$39.95	$86.95
Januvia	$117.24	$38.57	$16.19	$71.8
Entresto	$313.50	$139.26	$63.91	$162.31
Enbrel	2335.07	$734.24	$457.17	$1049
Imbruvica	$10619.31	$5669.95	$4957.54	$6615.08
Stelara	$4489.82	$2822.16	$1502.36	$5158.45
NovoLog/Fiasp	$134.35	$50.01	$26.59	$111.46

Notes: The average price for the 11 comparison countries is unweighted. For certain drugs, data are not available for all countries. See Tevis et al, for more details on methodology.

Conclusions

25. My analysis leads to a clear conclusion that both CMS and manufacturers would bear significant costs from a failed negotiation. Therefore, both parties have strong incentives to negotiate. To the extent that Professor Garthwaite suggests that CMS holds unfettered power to set any price that it wants, including a price at or near zero, that conclusion is unsupported by standard economic logic and inconsistent with the actual results from the first cycle of negotiations.

Thomas C. Buchmueller
April 21, 2025

Appendix A

April 2025

THOMAS C. BUCHMUELLER

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DEGREES

Ph.D. in Economics, University of Wisconsin-Madison, December 1992
B.A. Cum Laude, Distinction in Economics, Carleton College, 1985

ACADEMIC AND GOVERNMENT POSITIONS

2006 -	University of Michigan, Ross School of Business Waldo O. Hildebrand Professor of Risk Management and Insurance Senior Associate Dean for Faculty and Research, 2020-2023 Chair, Business Economics and Public Policy, 2012-2019
2007-	University of Michigan, School of Public Health. Professor of Health Management and Policy
2025-	The Brookings Institution, Center for Health Policy, Visiting Fellow
2023-2024	US Department of Health and Human Services, Deputy Assistant Secretary for Planning and Evaluation, Office of Health Policy
2019-2020	USC Schaeffer Center for Health Policy & Economics, Visiting Scholar
2015-2016	University of Bordeaux, Institut de Santé Publique, d'Epidémologie et de Développement, Professeur Invité
2011-2012	White House Council of Economic Advisers, Senior Health Economist
2006-2007	University of Technology, Sydney, Centre for Health Economics Research and Evaluation. Packer Policy Fellow
2005-2006	Federal Reserve Bank of San Francisco, Visiting Scholar
1992-2006	University of California, Irvine, Paul Merage School of Business. Professor, Economic and Public Policy (2005-2006); Associate Professor (1999-2005); Assistant Professor (1992-1999)
2001-2002	INSEAD, Healthcare Management Initiative. Visiting Research Scholar

2001-2003	Centre de Récherche d'Etude et de Documentation en Economie de la Santé. Visiting Researcher
1999-	National Bureau of Economic Research. Faculty Research Fellow (1999-2004); Research Associate (2004-)
1997	Centre for Health Economics, University of York (UK). Visiting Research Fellow

RESEARCH PUBLICATIONS

Journal Articles

"Estimating the Impact of Medicaid Loss on Prescription Drug Utilization: Lessons from the Public Health Emergency "Unwinding," with Eden Volkov, Jessica Eloso, Arielle Bosworth and Kenneth Finegold, *Health Affairs*, (forthcoming, 2025).

"The Impact of Health Insurance on Mortality," with Helen G. Levy, *Annual Review of Public Health*, (2025) 46:541-550.

"Health Outcome Changes in Individuals with Type 1 Diabetes After a State-Level Insulin Copayment Cap," *JAMA Network Open*, with Theodoros Giannouchos and Benjamin Ukert (2024) 7(8).

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"The Effect of Small Group and Individual Health Insurance Market Reforms on Insurance Coverage," (co-principal investigator with John DiNardo) California Policy Seminar (1998) $25,000.

"An Empirical Investigation of Health Plan Switching Under Managed Competition," (co-principal investigator with Paul J. Feldstein) Robert Wood Johnson Foundation/Changes in Health Care Financing and Organization (1996) $290,000.

"Small Group Health Insurance Reform in California: An Economic Analysis of Assembly Bill 1672," Kaiser Family Foundation (1995) $70,000.

"Evaluation of California's Small Group Market Health Insurance Reforms in the Context of National Trends in the Industry", Kaiser Family Foundation (1995) $30,000.

"Hospital Ownership and the Provision of Care to the Poor: An Analysis using the 1992 California Birth Cohort File," Aspen Institute (1995) $9,050.

"Early Childhood Immunization Incentive Payment Study," (co-principal investigator with Paul J. Feldstein) Irvine Health Foundation (1995) $13,010.

AWARDS AND FELLOWSHIPS

Health Services Research 2022 John M. Eisenberg Article of the Year (for "Hospital-Physician Integration and Medicare's Site-Based Outpatient Payments," with Brady Post, Edward Norton, Brent

Hollenback and Andrew Ryan)

Medical Care Research and Review, 2018 Paper of the Year (for "Vertical Integration of Hospitals and Physicians: Economic Theory and Empirical Evidence on Spending and Quality," with Brady Post and Andrew Ryan.)

AcademyHealth Noteworthy Article of 2011 (for "The Effect of an Employer Health Insurance Mandate on Health Insurance Coverage and the Demand for Labor: Evidence from Hawaii," with John DiNardo and Robert Valletta)

AcademyHealth Article of the Year, 2005 (for "The Effect of the State Children's Health Insurance Program on Health Insurance Coverage," with Anthony T. LoSasso)

Conexant Teaching Award for Outstanding Instructor in the MBA Core 2004

Best Instructor Award, MBA Core, 2004

International Society for Research in Healthcare Financial Management, Best Paper Award 2001 (for "Switching Costs, Price Sensitivity and Health Plan Choice").

University of California, Irvine, Faculty Career Development Award, 1996.

Order of Omega, Panhellic and Interfraternity Council Teaching Award, 1993.

National Institute of Mental Health Training Fellowship, 1990-1992.

Harold Groves Prize for Best Paper in Public Economics, University of Wisconsin, 1989.

University Fellowship, University of Wisconsin, 1987-1988.

CONFERENCE PRESENTATIONS, INVITED SEMINARS (since 2010)

2024-2025: IRDES-LIRAES Workshop on Applied Health Economics and Policy Evaluation

2023-2024: ASHEcon, AcademyHealth

2022-23: IRDES-LIRAES Workshop on Applied Health Economics and Policy Evaluation

2021-22: Monash University

2020-2021: IRDES-LIRAES Workshop on Applied Health Economics and Policy Evaluation, Brookings Institution

2019-2020: Australian Health Economics Society, Université de Paris-Dauphine, University of Southern California, Georgia State University

2018-2019: University of Georgia, Ohio State University, ASHEcon, International Workshop on Economics of Mental Health

2017-2018: University of Wisconsin-Madison, Association for Public Policy Analysis and Management, University of California-Irvine, University of Technology, Sydney

2016-2017: University of Chicago, Texas A&M University, University of California-Irvine, Upjohn Institute, University of Technology-Sydney, University of Southern California, Association Française de Science Economique, IRDES (Paris)

2015-2016: University of Bordeaux, University of Paris-Dauphine, Erasmus University, KU Leuven, Hospinnomics (Paris), College des Economistes de la Santé, CPB Netherlands Bureau for Economic Policy Analysis

2014-2015: Labor and Employment Relations Association, Association for Public Policy Analysis and Management, IRDES (Paris), Urban Institute, Carleton College

2013-2014: Indiana University, University of Minnesota, Case Western University, University of Darmstadt, Urban Institute, Carleton College, Gettysburg College, Association Française de Science Economique, International Industrial Organization Society, Association for Public Policy Analysis and Management

2012-2013: Carnegie Mellon University, Duke University, Vanderbilt University, American Economic Association, International Industrial Organization Society, Les Journées Louis-André Gérard-Varet (Marseille)

2010-2011: Rutgers University, Georgia State University, Johns Hopkins University, Yale University, Les Journées Louis-André Gérard-Varet (Marseille), OECD, University of New South Wales, University of Pennsylvania, University of Paris-Dauphine

PROFESSIONAL SERVICE, AFFILIATIONS
Member AHRQ National Advisory Council, 2023-2024

Member American Society of Health Economics, Board of Directors, 2014-2023

Member National Academy of Social Insurance, 2014-

Chair AcademyHealth, Health Economics Interest Group, 2007-2008

Editor-in-Chief *American Journal of Health Economics*, 2018-2023

Deputy Editor *Medical Care,* 2002-2006

Co-Editor *Journal of Economics and Management Strategy,* 2004- 2010

Editor *Berkeley Electronic Journal of Economic Analysis and Policy*, 2008-2012

Editorial Board *Inquiry*, 2003-
Geneva Papers on Risk and Insurance—Issues and Practice, 2009-
American Journal of Health Economics, 2014-2018

Reviewer—Journals
American Economic Review, American Economic Journal—Applied Economics, American Economic Journal—Economic Policy, American Journal of Managed Care, Annals of Internal Medicine, Applied

Economics, Berkeley Electronic Journal of Economic Analysis and Policy, Contemporary Economic Policy, Economic Inquiry, Economic Journal, European Economic Review, Health Affairs, Health Economics, Health Policy, Health Services Research, Industrial and Labor Relations Review, Industrial Relations, Inquiry, International Journal of Health Care Finance and Economics, Journal of Economic Behavior & Organization, Journal of Economic Education, Journal of Economics, Management and Strategy, Journal of Health Care for the Poor and Underserved, Journal of Health Economics, Journal of Human Resources, Journal of Mental Health Policy and Economics, Journal of Labor Economics, Journal of Political Economy, Journal of Public Economics, Journal of Risk and Insurance, Journal of Urban Economics, Management Science, Medical Care, The Milbank Quarterly, Public Management, Review of Economics of the Household, Social Science & Medicine, Southern Economic Journal

Reviewer—Grant Programs
Academy for Health Services Research and Health Policy, Agency for Health Care Research and Quality, Aspen Institute Nonprofit Research Fund, California Policy Research Center, California Program on Access to Care, National Institute on Aging, National Science Foundation, Republic of Ireland Health Research Board, Robert Wood Johnson Foundation HCFO, Russell Sage Foundation, Swiss National Science Foundation

Conference Organizer
Consumer Choice & Competition in Health Insurance Markets: An International Perspective, 2003
Louis and Myrtle Moskowitz Workshop on Empirical Health Law and Business Research, 2010
American Health Econometrics Workshop, 2010
Midwest Health Economics Conference, 2011, 2019

TEACHING (Selected)
Microeconomics for Management
Health Care Markets and Public Policies
Health Care Public Policy
Economics of Insurance

SCHOOL AND UNIVERSITY SERVICE (Selected, Since 2007)
Ross School of Business
- Executive Committee, 2010-2011; 2017-2019
- Business Economics and Public Policy Area Chair, 2012-2019
- Business Economics and Public Policy PhD Program Director, 2009-2011

Institute for Health Policy and Innovation
- Institutional Leadership Team, 2012-2018

Search Committee for Executive Vice President of Medical Affairs, 2015

University of Michigan Health Benefits Program
- Medical Benefits Advisory Committee, 2015-2019
- MHealthy Advisory Committee, 2009-2015
- Member Engagement Health Plan Committee, 2010-2011
- Committee on Retiree Health Benefits, 2009-2010
- Committee on Sustainable Health Benefits, 2008-2009

Appendix B

Appendix B: Resources Relied Upon

Adams, Christopher and Evan Herrnstadt, "CBO's Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act," Congressional Budget Office Working Paper 2021-01, available at https://www.cbo.gov/publication/56905.

Anderson-Cook, Anna and Richard G. Frank, "Impact of Federal Negotiation of Prescription Drug Prices," The Brookings Institution (August 19, 2024), available at https://www.brookings.edu/articles/impact-of-federal-negotiation-of-prescription-drug-prices/.

ASPE, Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs, Inflation Reduction Act Research Series, December 14, 2023.

Chandra, A., Gruber, J. and McKnight, R., 2010. Patient cost-sharing and hospitalization offsets in the elderly. *American Economic Review*, 100(1), pp.193-213.

Chen, Jennifer C., Nancy Le, Steve Jang and Anna Koeltenboeck, "What Medicare Negotiation Tells Us About Drug Pricing in the U.S.," *Health Affairs Forefront*, (2024), available at https://www.healthaffairs.org/content/forefront/medicare-negotiation-tells-us-drug-pricing-u-s.

Congressional Budget Office, letter to the Honorable Ron Wyden (April 10, 2007), www.cbo.gov/publication/18550.

Congressional Budget Office, letter to the Honorable Chuck Grassley (May 17, 2019), www.cbo.gov/publication/55270.

Frank, Richard G. and Gerald F. Anderson, letter to Meena Seshamani commenting on Medicare Drug Price Negotiation Program Draft Guidance (July 1, 2024). https://www.brookings.edu/articles/comments-on-the-medicare-drug-price-negotiation-program/.

Frank, Richard G., and Len M. Nichols. "Medicare drug-price negotiation—why now... and how." *New England Journal of Medicine* 381, no. 15 (2019): 1404-1406.

Hernandez, Inmaculada, Emma M. Cousin Olivier J. Wouters, Nico Gabriel, Teresa Cameron and Sean D. Sullivan, "Price Benchmarks of Drugs Selected for Medicare Price Negotiations and their Therapeutic Alternatives," *Journal of Managed Care Specialty Pharmacy*, 30 no. 8 (2024): 762-772.

Hernandez, Inmaculada, Olivier J. Wouters, Emma M. Cousin, Ayuri S. Kirihennedige and Sean D. Sullivan, "Interpreting The First Round of Maximum Fair Prices Negotiated By Medicare For Drugs," *Health Affairs Forefront*, (2024), available at https://www.healthaffairs.org/content/forefront/interpreting-first-round-maximum-fair-prices-negotiated-medicare-drugs.

Hsu, J., Price, M., Huang, J., Brand, R., Fung, V., Hui, R., Fireman, B., Newhouse, J.P. and Selby, J.V., 2006. Unintended consequences of caps on Medicare drug benefits. *New England Journal of Medicine*, *354*(22), pp.2349-2359

Kakani, Pragya, Michael Anne Kyle, Amitabh Chandra, and Luca Maini, "Medicare Part D Protected-Class Policy is Associated with Lower Drug Rebates, *Health Affairs*, 43 no. 10 (2024): 1420-1427.

Lakdawalla, Darius, "Economics of the Pharmaceutical Industry," *Journal of Economic Literature*, 56 no. 2 (2018): 397-449.

Sarah Owermohle and Sarah Karlin-Smith, "Patient groups, pharma cheer CMS retreat on protected class change," *Politico* (May 17, 2019).

Rodwin, Marc A. and John D. Lantos, "How Will Medicare Negotiate Drug Prices, And What Impact Will It Have?" *Health Affairs Forefront*, (2024), available at https://www.healthaffairs.org/content/forefront/medicare-negotiate-drug-prices-and-impact-have.

Tevis, Delaney, Matthew McGough, Juliette Cubanski and Cynthia Cox, How Medicare Negotiated Drug Prices Compare to Other Countries, Peterson-KFF Health System Tracker, December 19, 2024, available at: https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/

Wouters, Olivier J., Sean D. Sullivan, Emma M. Cousin, Nico Gabriel, Irene Papanicolas, and Inmaculada Hernandez. "Drug Prices Negotiated by Medicare vs US Net Prices and Prices in Other Countries." *JAMA* 333, no. 1 (2025): 85-87.

Zhang, Y., Donohue, J.M., Lave, J.R., O'Donnell, G. and Newhouse, J.P., 2009. The effect of Medicare Part D on drug and medical spending. *New England Journal of Medicine*, *361*(1), pp.52-61,

Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, Proposed Rule, Center for Medicare & Medicaid Services, 42 CFR Parts 422 and 423 (November 30, 2018), available at https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses.

Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, Final Rule, Center for Medicare & Medicaid Services, 42 CFR Parts 422 and 423 (May 23, 2019), available at https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses.

https://www.congress.gov/bill/116th-congress/house-bill/3.

https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.